

Starting a Fresh Cut Light Produce Processing Business

Presented by:
Iowa Food Safety Task
Iowa State University Extension
Iowa Department of Inspections and Appeals and
Iowa Department of Public Health

Overview

- Copy of the powerpoint presentation is available at the following location:
 - <http://www.dia.iowa.gov/page23.html>
- This presentation is being recorded and will be made available online. We will notify all registrants once it has been posted.

Overview of Licensing

- Home Food Establishment
- Food Service Establishment
- Retail Food Establishment
- Food Processing Plant

Home Food Establishment

- A business on the premises of a resident in which prepared foods (bakery items only) are created for sale and the food is created off the premises.
 - Examples include soft pies, bakery products with a custard or cream filling. This does not include non hazardous baked good, including breads, fruit pies, cakes, and nonhazardous pastries.
 - Exceptions:
 - Residences where food is prepared to be used or sold by churches, fraternal societies, or charitable, civic or nonprofit organizations are not included.
 - Residences which prepare or distribute honey, shell eggs or nonhazardous baked goods are not required to be licensed as home food establishments.

Food Service Establishment

- An operation that stores, prepares, packages, services, and provides food for human consumption.
 - Examples may include a catering operation.

Retail Food Establishment

- Sells food or food products intended for preparation or consumption off the premises.

Food Processing Plant

- A commercial operation that manufactures, packages, and labels food for human consumption but does not provide for directly to a consumer.
- Today's webinar focuses on this type of licensing.
- License fee varies on the gross fee. For example, those with less than \$50,000 in gross sales is \$67.50.
- Meat and poultry processing cannot be conducted as a home-based business. This area is regulated by Iowa Department of Agriculture and Land Stewardship (IDALS)

Changes with the Food Safety Modernization Act

- In December 2010, Congress passed the Food Safety Modernization Act which largely relates to food processing.
- Most small processors (under \$500,000) will likely be exempt from much of the Act.

Other Considerations

- This presentation focuses on the requirement for licensure only. Some other things to consider include:
 - Product and personal liability insurance; and
 - Business planning including market assessment, cost and revenue estimates, and marketing.

Food-related diseases

- Affect tens of millions and kill thousands of people in the US every year
- Public health officials track single cases of foodborne illness and investigating outbreaks
 - Centers for Disease Control and Prevention
 - Iowa Department of Public Health
 - Local Public Health Departments (101 in Iowa)



U.S. Estimates of Foodborne Illness (2011)

- 1 out of every 6 people will get sick
- 128,000 will be hospitalized
- 3,000 will die

www.cdc.gov/foodborneburden/2011-foodborne-estimates.html



5 Most Common Foodborne Illnesses in the U.S.

- | | |
|--|-----------|
| • Norovirus (58%) | 5,461,731 |
| • <i>Salmonella</i> (11%) | 1,027,561 |
| • <i>Clostridium perfringens</i> (10%) | 965,958 |
| • <i>Campylobacter</i> spp. (9%) | 845,024 |
| • <i>Staphylococcus aureus</i> (3%) | 241,148 |



<http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>

Symptoms of Foodborne Illness

- Symptoms and severity vary by illness
- Commonly symptoms include:
 - Nausea, vomiting, abdominal cramps, & diarrhea
- Call healthcare provider when experiencing more severe symptoms, including:
 - High fever, bloody stools, prolonged vomiting, dehydration, dizziness

Vulnerable populations

- Some people are more vulnerable to developing severe illness:
 - Young children & elderly populations
 - Immuno-compromised individuals
 - Pregnant women are more susceptible to some illnesses



Nationwide Salsa & Guacamole Implicated More Often in Foodborne Outbreaks

- From 1998-2008
 - 1 of 25 restaurant-associated foodborne outbreaks traced to salsa or guacamole
 - Twice as many outbreaks as the previous decade
- Inappropriate storage & temperatures
- Ill food service workers

<http://www.cdc.gov/media/pressrel/2010/r100712.htm>



Fresh Cut Produce Products: Licensing Requirements

Scott Platt – Food Safety Specialist
Iowa Department of Inspections & Appeals
Food & Consumer Safety Bureau



Objectives & Overview

- Discuss licensing
- Identify governing regulations
- Identify specific licensing requirements
- Identify resources for interested parties



Licensing Process

- Determine if a license is needed
 - Direct consumer sales of raw unprocessed produce
 - Wholesales of processed produce
 - Light processing – trimming, cutting, freezing
 - Washing and repackaging
- What license type is needed?
 - Food Processing License



Licensing Process

- How is license obtained?
 - Obtain license application from DIA, Food & Consumer Safety Bureau
 - Submit application and fees, along with floor plan of proposed processing area.
 - Iowa administrative rules require application and fees to be submitted 30 days prior to opening.
 - Inspection of premises, process, and labels prior to opening business.



Governing Regulations

- Rules for operation of Food Processing Plants adopted in accordance with IA code – Chapter 31, 481- 31.2(137F)
 - 21 CFR (Code of Federal Regulations), Part 110 – Good Manufacturing Practices
 - 21 CFR, Part 113 – Low Acid Canned Foods
 - 21 CFR, Part 114 – Acidified Foods

** Note that 21 CFR Parts 113 or 114 may only apply if products are either canned or acidified.



Governing Regulations

- Other Things You Need to Know
 - IA code requires a separate processing facility
 - Kitchens in a private residence may not be used
 - Other areas in a private residence may qualify for licensing if approved by DIA.



Governing Regulations

- Other Things You Need to Know
 - Other Federal Regulations may apply, especially if finished products are wholesaled or distributed in interstate commerce.
 - Bioterrorism Act of 2002 – Facility Registration
 - FDA Food Defense Guidelines to encourage protection of raw materials and finished goods.



Licensing Requirements

- Basis for requirements
 - 21 CFR, Part 110 – Good Manufacturing Practices



Facility Requirements

- Plant & Grounds
 - Floors, walls, ceilings constructed so that they can be adequately cleaned & kept in good repair.
 - Lighting
 - Adequate number and intensity to ensure good cleaning practices.
 - Shielded, covered, or shatter resistant in areas with exposed foods, ingredients, or packaging materials.



Facility Requirements

- Ventilation
 - Adequate to minimize odors
 - Adequate to ventilate excessive heat
 - Adequate to reduce or eliminate excessive moisture and/or condensation.
- Doors, Outer Openings, & Windows
 - Tight Fitting – no gaps under doors
 - Adequate screening provided



Facility Requirements

- Grounds
 - Free from litter
 - Vegetation control – no excessive weeds or tall grass
 - Free from pooling water
- Roads, Yards, & Parking Lot
 - Maintained so that food is not contaminated.



Facility Requirements

- Water Safety
 - Municipal or private well water source?
 - Private well water sources must be tested annually for presence of bacteria (Coliforms & E. coli)
 - Municipal sources not required to be tested
 - May want to consider optional testing within plant to determine safety/quality of plumbing systems.
 - Some private well sources may need to be permitted as public water sources in accordance with IA DNR requirements.



Facility Requirements

- Equipment & Food Contact Surfaces
 - What is a Food Contact Surface?
 - Any surface which contacts human food & surfaces from which drainage onto food or onto surfaces that contact food ordinarily occurs during normal operations.
 - Designed & constructed of safe materials
 - Food grade materials

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Facility Requirements

- Equipment & Food Contact Surfaces
 - Designed & constructed for cleanability
 - Smooth, non-porous, constructed from materials which can withstand multiple cleaning and exposure to cleaning compounds.
 - Free from rough edges and seams
 - Free from chips, pits, cracks, and other similar imperfections that would make cleaning difficult.
 - Suitable for their intended use.
- ** Note: Gloves may be considered food contact surfaces, dependant upon application of use.

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Facility Requirements

- Hand Sinks & Toilets
 - Hand washing stations
 - Adequate number provided
 - Conveniently located so as to promote & facilitate frequent hand washing.
 - Must have a supply of hot and cold water.
 - Toilet Facilities
 - Adequate number provided
 - Easily accessible
 - Equipped with self-closing doors

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Facility Requirements

- Sanitation
 - Capable of demonstrating adequate methods/procedures for washing and sanitizing equipment and utensils.
 - Programs/procedures for cleaning facilities
 - Manual or mechanical washing machine/sinks provided.
 - Domestic or home style dishwashing machines do not meet requirements.



Facility Requirements

- Sanitation continued
 - Sanitizers
 - Must be approved for use on food contact surfaces
 - Personnel trained to mix and test concentrations
 - Method to validate that sanitizer is mixed at appropriate concentration
 - Criteria for sanitizers specified in 40 CFR 180.940
 - Master cleaning schedule recommended
 - Standard Operating Procedures for cleaning & sanitizing equipment recommended.



Other Requirements

- Processes and Process Controls
 - Must be adequate to ensure foods are free from contamination, filth, foreign material, and other forms of adulteration.
 - Each process must be evaluated independently



Other Requirements

- Processes and Process Controls cont.
 - Process approval based upon multiple variables
 - Product produced
 - Method(s) of production
 - Preservation and shelf life
 - Specific rules governing special processes (canning or acidification)?



Other Requirements

- Pest Control
 - Program to ensure exclusions of insects, pests, birds, animals, and etc.
 - Pesticides used are approved and applied in safe manner.
- Sewage and Waste
 - Disposed of in accordance with state and/or local laws.
 - Disposed of via an approved system.



Other Requirements

- Scales & other process control instruments
 - Maintain accuracy
 - Calibrated at frequencies to maintain accuracy
 - Documentation of verifications/calibrations maintained on file.
- Compressed Gases or Air
 - If used in direct contact with food, equipment, or utensils – meet requirements for food grade applications



Other Requirements

- Lubricants
 - Food grade if incidental contact with food, equipment, utensils, or food contact surfaces.
- Use & Storage of Toxic items
 - Product is labeled as approved for use in food processing facility.
 - Product is used in accordance with manufacturer's labeling instructions.
 - Product is stored so as to prevent contamination of foods, equipment, packaging materials, etc.
 - Recommend a secured separate storage area, with controlled access to area and authorized personnel only.



Other Requirements

- Recalls / Consumer Complaints
 - Recommend written procedures for how instances are handled and resolved
 - Distribution of finished goods
 - Adequate records maintained to determine location of finished product



Other Requirements

- Personnel
 - Training programs developed and implemented to adequately train personnel with regards to GMPs
 - Good personal hygienic practices
 - Responsibility to report forms of communicable diseases to supervisors
 - Documentation maintained to demonstrate that training is done.
 - Provide adequate areas for storage of personal belongings.
 - Provide adequate areas for breaks, consumption of beverages and food.



Resources

- Iowa Department of Inspection & Appeals
 - Food & Consumer Safety Bureau
 - <http://dia.iowa.gov/page3.html>
- Code of Federal Regulations
 - 21 CFR – Food & Drugs
 - <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>
- FDA
 - FDA Home Page
 - <http://www.fda.gov>
 - Food Labeling Guidance Document
 - <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm>



Resources

- FDA cont.
 - Guide to Minimizing Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables
 - <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM064458>
 - Food Defense Guidance Document
 - <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083075.htm>



Resources

- FDA cont.
 - Bioterrorism Act & Facility Registration
 - <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/UCM113877.pdf>



Resources

- FDA Small Business Representative – SW Region Office

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Fresh Cut Produce Products: Procurement and Handling Best Practices

Catherine Strohbehn, PhD, RD, CP-FS

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We know where the product came from – but how was it produced?

- One advantage of local foods is we know where the product was sourced
- It is also important to know whether good agricultural practices (GAPs) were followed.
- Some producers have taken training on GAPs and/or other types of on-farm food safety.
- FDA has developed a Guide to Minimize Risks Fresh Fruits and Vegetables
- A checklist has been developed as a guide for buyers to “begin the conversation” with producers.

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Contains Nonbinding Recommendations
October 26, 1998

USDA, ARS, AND FDA

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

U.S. Department of Agriculture • U.S. Food and Drug Administration

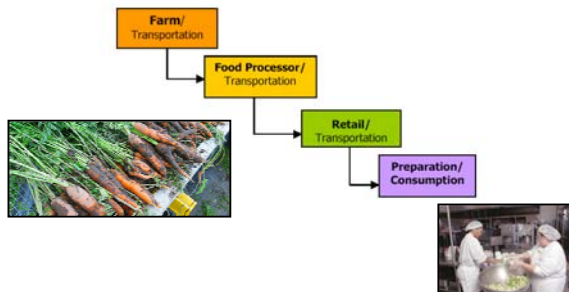
Center for Food Safety and Inspection Service • Food Safety and Inspection Service

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- Produce flow begins on the farm
- Growers need to be aware of control points and steps to mitigate risks
- Processors need to take action at strategic points
- Consumers/foodservices also need to take action

Vulnerabilities Exist Throughout the Food Supply Chain:



Processing Food Flow

- Purchasing of raw ingredients
- Receiving
- Storage until use
- Handling and Product preparation
- Packaging
- Storage of Packaged Products
- Distribution

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Processors ask about Grower Documentation

- Is there a food safety plan?
- Is there GAPs certification or food safety training?
- Is there awareness and concern about risks?
- Have you visited the farm?



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Elements of a farm food safety plan

- Manure storage and handling
- Animal exclusion (domestic & wild)
- Irrigation and drainage management
- Equipment sanitation
- Harvest and post harvest handling
- Employee training program
- Restroom & hand washing facilities
- Crisis management strategy

Record It or Regret It !

Processors should also ask Growers about Controls Human Contamination

1. Worker hygiene
2. Worker Health
3. Post harvesting processing practices
4. Temperature controls
5. Facilities control
6. Wash water

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**Fresh Produce Growers
and Packers
ARE Food Handlers !!!**

- In this example, workers have protective clothing and hair is restrained while they harvest produce.
- We assume they have no communicable illness.



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How is fresh produce delivered to processing? The transportation link

- Ownership of product until transferred
- Precautions taken during transit
- Food contact surfaces – grower packages and transit vehicle
- Time and temperature abuse
- Protection product integrity – potential for unintentional or intentional contamination



Time and Temperature Monitoring – some examples



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Receiving – Check for quality and Quantity

- Once you accept the product – it is yours
- Traceability is required at least one step back of the food chain
- Documentation



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Storage of Raw Ingredients

- Produce storage is not one-size-fits all!
- Each product has own specific temperature and humidity levels recommended
- Can collapse into storage temperature ranges:
 - cold and wet (i.e. broccoli) – below 41 F
 - cold and dry
 - tropical (i.e tomatoes and bananas)

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Handling/Preparing Product. Establish SOPs

- Establish Work Zones – cleaning, preparing and storage of products
- Avoid cross contamination knives, containers, and other processing equipment
- Enforce Worker Health Status/Hygiene Practices
- Enforce Worker Hygiene.
- Supplies and facilities for handwashing
- Proper glove use –
 - Uniforms/aprons worn appropriately
- Clean and Sanitize Equipment.

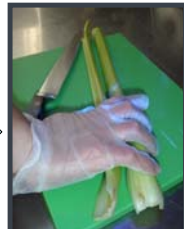


Yuck Photos – Cross contamination in action



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Fundamental!



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Proper glove use



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•What could go wrong?



Gloved Hand to Cutting Board



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Cutting Board to Celery



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Preparing Produce

- Product cleaning procedures specific to item
- In general, wash thoroughly under running water before cutting or combining with other ingredients
 - Use water slightly warmer (10 F°) than the temperature of the produce
 - Pull leafy greens apart and rinse thoroughly
 - Drain produce well before packaging
 - Clean and sanitize surfaces used to prepare produce

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Preparing Produce - Do's and Don'ts

- **Don't** mix in soaking water:
 - Different items
 - Multiple batches of the same item
- **Do** refrigerate and hold cut melons, tomatoes and salad greens at 45°F (5°C) or below as appropriate for that food
- **Don't** add sulfites
- **Do** follow regulations seed sprouts and mushrooms

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Packaging Steps

- Methods and Practices
 - Adopt methods and practices which will prevent post processing contamination.
 - Prevention of bare hand contact with ready-to-eat foods is strongly encouraged.
- Packaging Materials
 - Must be safe and consist of materials as approved in 21 CFR Parts 175, 176 and/or 177.

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Packaging Steps

- Packaging Materials cont.
 - Provide protection during handling/distribution
 - Protection from poor environmental conditions
 - Protection from mechanical damage

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Packaging Steps

- Examples of packaging materials used
 - Bulk Packaging Methods
 - Palletized bins
 - Wire-bound crates
 - Wooden crates & lugs
 - Wooden baskets & hamper

** If treated wood is used, must be treated with food grade substances.

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Packaging Steps

- Bulk Packaging cont.
 - Corrugated fiberboard
 - Pulp containers
 - Paper and mesh bags
- Retail Sales / Individual consumer
 - Plastic bags
 - Shrink wrap
 - Rigid plastic containers/packages

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Packaging Steps

- Temperature Controls
 - Dependant upon quality and/or safety factors
- Quality Controls
 - More or less refrigeration based upon sensitivity of fruit or vegetable. Some varieties more susceptible to chill damage and deterioration in colder temps. (Tomatoes/Bananas)
 - Refrigeration helps to prolong shelf-life.

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Packaging Steps

- Temperature Controls cont.
 - Safety Controls
 - Is refrigeration required for safety purposes to limit potential growth of pathogenic bacteria (E. coli and sprouts)?
 - Refrigeration temperature as specified in 21 CFR Part 110 is 45 F.
 - Retail industry requires refrigeration temp of 41 F or less for receipt and storage, unless governing laws specify otherwise.

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Packaging Steps

- Inventory Management
 - Rotation of Product
 - Practice of FIFO principle (First-In-First-Out)
 - System for tracking and maintaining accountability of product (Traceback)
 - Includes product on-hand or in storage
 - Products in distribution, and location of

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Packaging Steps

- Labeling
 - State requirements adopted from federal requirements.
 - Federal requirements for labeling are specified in 21 CFR, Part 101.

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Packaging Steps

- Labeling cont.
 - Basic Labeling Requirements for retail packages
 - Identify product by name, common name, or fanciful name
 - Name and address of the manufacturer, packager, or distributor (Complete mailing address required)

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Packaging Steps

- Complete listing of ingredient content if more than one ingredient is present
 - Most predominate to least predominate ingredient
 - FD&C certified colors must be declared (i.e. Red #40, Yellow #5)
 - Sulfites in concentrations of 10 ppm or greater
 - Allergens

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Packaging Steps

- Labeling continued
 - Declaration of contents by weight, volume, or count.
 - Nutritional Facts Paneling
 - Must be provided unless qualifies for exemption
 - Must be provided if nutritional or health claims are made on product labels.
 - May include vignettes or information on web pages

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Packaging Steps

- Nutritional Facts cont.
 - Firms may be exempt based on one of the following conditions, but must file a notice with FDA seeking such exemption
 - Less than 10,000 units sold annually and employs than 10 full-time employees
 - Less than 100,000 units sold annually and employs than 100 full-time employees

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Packaging Steps

- Labeling continued
 - Allergens
 - FDA recognizes 8 common allergens
 - Peanuts, Wheat, Milk, Soy, Eggs, Tree Nuts, Shellfish, & Fish
 - Must be declared on the label in the ingredients statement, or in a “Contains” statement
 - Must be declared by their common name (i.e. Milk, eggs, soy, wheat, almonds).
 - Must be declared on label even if included as trace amounts either added by the manufacturer, or due to ingredients used from a supplier.

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Storage of Prepared Products

- Most under 41 F
- Maintain inventory
- Rotate stock
- Follow principles FIFP
- Keep off the ground -

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Distribution of Packaged Product

- Transportation should protect quality and integrity of product
- Containers and vehicles should be clean



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Protecting Produce on the Move

- **Inspect trucks prior to loading to ensure cleanliness and proper refrigeration.**
- **Identify prior loads hauled in the truck. Trucks that have hauled raw animal products should be avoided due to the risk of cross contamination.**
- **Document truck temperature, cleanliness, and state of product at time of shipment.**

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Traceback and Positive Lot Identification

Manual or computer based



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What Day? What Lot? Who worked?

- Lot identification aids in tracing back any problems that develop.
- For example, reports of Hepatitis A made by consumers of packaged broccoli. Can trace back to workers and pinpoint who is ill. Can minimize product loss.
- *It is always better to be **proactive and prepared** than **reactive and confused**.*

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Elements of food processing safety plan

- Facility and equipment maintenance records
- Worker health and hygiene policies (SOPs)
- Uniform policies
- Cleaning and sanitizing
- Monitoring and verification records
- Restroom & hand washing facilities
- Crisis management strategy

Record It or Regret It !

If you did not RECORD IT,
you did not do it.

- Record keeping allows you to better manage facilities, employees and operations.
- Record keeping documents your activities and preventative care taken. It shows you care!

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Farm to Fork Fresh Cuts



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